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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/993,669

11/27/2001

Ann-Kristin Karlsson

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10/21/2003

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EXAMINER

MAIER, LEIGH C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 10/21/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,669

Applicant(s)

KARLSSON ET AL.

Examiner

Leigh C. Maier

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 7-25-03
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,8,9,14,30-35,37-52,54 and 56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,8,9,14,30-35,37-52,54 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. 09/230,781.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Status of the Claims

Claims 36 and 53 have been canceled. Claim 56 has been added. Claims 3, 8, and 9 have been amended. Claims 3, 8, 9, 14, and 30-35, 37-52, 54, and 56 are pending. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any objection or rejection not expressly repeated has been withdrawn.

Claim Rejections - 35 USC § 112 – second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim depends from claim 51 and recites “the particle has the same pharmacological activity and physico-chemical properties, chemical purity and physical form as the particles before sterilization.” However, these properties are not defined in either claim, thereby rendering the claim vague and indefinite. This type of limitation might be acceptable in a process claim, but in a product claim, the product must be defined in such a way that makes it identifiable in the absence of knowledge of its method of production or precursor.

Claim Rejections - 35 U.S.C. § 103

Claims 3, 4, 6, 34, 35, 39, 41, 42, 45-47, and 49-52 are again rejected under 35 U.S.C. 103(a) as being unpatentable over JAKUPOVIC et al (WO 96/32095) and BUSSEY et al (J. Parenter. Sci. Tech., 1983), as set forth in the previous Office action. New claim 56 is also rejected over this combination of references.

Independent claim 3 has been amended to change the position of the limitation "heat sterilized." This amendment does not change the substance of the claim. Claim 9 has been amended to change "formulation" to "suspension" to be consistent with claim 8 from which it depends. Dependent claims recite limitations as set forth in the previous Office action.

Applicant's arguments filed July 25, 2003 have been fully considered but they are not persuasive.

With regard to claims 3, 49, 50, and 52 (and dependents), Applicant first notes that neither reference teaches every limitation of the invention. The examiner agrees. The rejection is based on the combination of the references. Applicant cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant further contends that the motivation [to combine references] is not related to the teaching of either reference. The examiner disagrees. As previously discussed, JAKUPOVIC clearly teaches respirable particles. BUSSEY teaches the desirability of sterile pharmaceutical products.

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Applicant states that claims 3, 49, 50, and 52 are pure product claims, not product-by-process claims. Applicant further cites case law stating that the “limitation, read in context, describes the product more by its structure than by the process used to obtain it.” This is consistent with what the examiner has maintained throughout prosecution. Although the claims are *written* as product-by-process, the determination of patentability is based on the product itself. It is the Applicant who continues to emphasize the criticality of the “heat sterilized” part of the claim. However, the burden remains on Applicant to show a measurable difference between “heat sterilized” product and one sterilized in another manner.

Applicant argues that the product produced by heat sterilization has greater purity than that produced by irradiation. The examiner agrees that the specification discloses data that appears to support this for a single species, budesonide, but it is not clear that the difference (99.1 vs 99.2) is significant and reproducible or commensurate with the scope of the claims. Also, this only compares irradiation but does not take into consideration sterilization by ethylene oxide.

With regard to independent claims 39 and 51, Applicant contends that the combination of references does not teach particles being sterilized by heat treatment. The examiner directs Applicant to their cited case law that states that the claim is to be interpreted as reciting a pure product. The product must stand as a patentably distinct entity that is measurably different from a product that would be obvious from the combination of JAKUPOVIC and BUSSEY.

With regard to claim 54, this claim was not previously rejected over these two references alone. It was rejected in further view of SEQUIEIRA. See page 3 of previous Office action.

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With regard to newly added claim 56, the claim is another product-by-process claim that would depend on what the starting substrate was. The combination of references above teach the production of sterile glucocorticosteroids by irradiation treatment that may result in some chemical degradation. However, a compound that, after irradiation sterilization, is 99% pure is indistinguishable from one that is heat sterilized and is also 99% pure. Applicant has not yet established that a heat-sterilized glucocorticosteroid is a product that is measurably distinct from one that is sterilized by a different method.

Claims 8-12, 14, 30, 31, 43, 44, 48, and 54 are again rejected under 35 U.S.C. 103(a) as being unpatentable over JAKUPOVIC et al (WO 96/32095) and BUSSEY et al (J. Parenter. Sci. Tech., 1983) as applied to claims 3, 4, 6, 34, 35, 39, 41, 42, 45-47, 49-52, and 56 above, in view of SEQUIEIRA et al (US 5,837,699), as set forth in the previous Office action.

Claims 32, 33, and 40 are again rejected under 35 U.S.C. 103(a) as being unpatentable over JAKUPOVIC et al (WO 96/32095) and BUSSEY et al (J. Parenter. Sci. Tech., 1983) as applied to 3, 4, 6, 34, 35, 39, 41, 42, 45-47, 49-52, and 56 above, and in further view of RADHAKRISHNAN et al (US 5,192,528), as set forth in the previous Office action.

Claims 8, 11, and 37 are again rejected under 35 U.S.C. 103(a) as being unpatentable over JAKUPOVIC et al (WO 96/32095) and BUSSEY et al (J. Parenter. Sci. Tech., 1983) as applied to claims 3, 4, 6, 34, 36, 39, 41, 42, 45-47, 49-52, and 56 above, in view of SEQUIEIRA et al (US 5,837,699) and RADHAKRISHNAN et al (US 5,192,528), as set forth in the previous Office action.

Applicant's arguments filed July 25, 2003 have been fully considered but they are not persuasive.

Applicant contends that JAKUPOVIC and BUSSEY do not teach or suggest an inhalation powder in the form of finely divided heat-sterilized particles as set forth in the independent claims. The examiner maintains that the combination of references do present a *prima facie* case for obviousness, and Applicant's arguments are addressed above. Applicant further contends that the other references do not remedy the supposed deficiencies in JAKUPOVIC and BUSSEY.

Applicant contends that RADHAKRISHNAN does not teach an inhalation powder or suspension of the recited particles. As clearly stated in the previous Office action, this reference was used to teach desirable particle sizes for formulations designed to reach the lower respiratory tract.

Applicant contends that SEQUIEIRA does not teach an inhalation powder or a suspension of sterilized particles including the recited compounds. As previously discussed, SEQUIEIRA teaches the administration of glucocorticosteroids as a dry powder or aqueous suspension, exemplifying mometasone but establishing functional equivalence between mometasone and other glucocorticosteroids, such as budesonide. It would have been obvious to prepare an inhalation powder or suspension, comprising a sterile particle, of any of these compounds known to have the same utility in the treatment of respiratory disorders.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

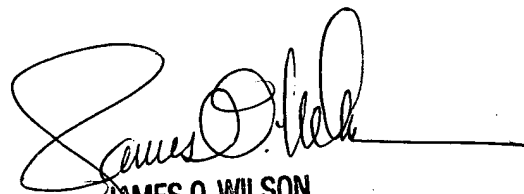
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, or Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
October 17, 2003


JAMES O. WILSON
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